

REMARKS

Claims 63 and 65-75 are the pending claims in the present application. Applicants cancel, without prejudice, claim 69. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action. Applicants apologize for any confusion caused by the submission filed August 5, 2004, in which certain claims contained an improper claim identifier.

1. Applicants note with appreciation that the finality of the previous Office Action has been withdrawn in light of the request for continued examination filed April 5, 2004. Claims 63 and 65-75 are pending and under consideration.

2-3. Claims 63 and 65-68 are rejected under 35 U.S.C. 102(a) as allegedly anticipated by Ingham et al. Claims 63 and 65-68 are further rejected under 35 U.S.C. 103(a) as allegedly obvious in light of Ingham et al. Applicants traverse these rejections and contend that the rejections are moot in light of the amended claims.

Applicants maintain the arguments of record and contend that Ingham et al. fail to undermine the patentability of the claimed subject matter. Nevertheless, to expedite prosecution, Applicants have amended the claims to incorporate the features of previously pending claim 69 which specifies that the claimed preparation comprises a post-translationally modified hedgehog polypeptide, and specifically a hedgehog polypeptide post-translationally modified with one or more lipophilic or hydrophobic moieties. Applicants note that claim 69 has not been indicated by the Examiner as rejected under either 35 U.S.C. 102(a) or 35 U.S.C. 103(a), and thus Applicants contend that incorporation of the novel and inventive features of claim 69 into claim 63 (and thus into claims dependent upon claim 63) obviates the rejections. Applicants' amendments are not in acquiescence to the rejections, and Applicants reserve the right to prosecute claims of similar or differing scope.

Applicants contend, as outlined in detail above, that Applicants' amendments to the claims to incorporate the novel and inventive features of claim 69 obviates these rejections and places the pending claims in condition for allowance. Nevertheless, to further clarify the record, Applicants briefly outline below the reasoning in support of Applicants' position that the

amended claims are novel and inventive in light of the prior art, as provided by the MPEP and the Federal Circuit.

Ingham et al. fail to satisfy the criteria for anticipating Applicants' invention. Both the MPEP and the Federal Circuit support Applicants' contention that in order to anticipate or render obvious the claimed invention, the cited art must teach all the limitations of the claimed subject matter (MPEP 2131). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegall Bros. v. Union Oil Company of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ3d 1913, 1920 (Fed. Cir. 1989). The Ingham et al. application fails to teach the particular combination of elements of the pending claims. Specifically, Ingham et al. fail to teach the particular combination of a modified hedgehog polypeptide formulated in a preparation for topical application. Accordingly Ingham et al. fail to anticipate the claimed invention, and Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 102(a).

The Office Action alleges that even if, *arguendo*, Ingham et al. fail to anticipate the claimed invention, the teachings of Ingham et al. render the claimed invention obvious. Applicants respectfully disagree.

Applicants contend that a valid patent may issue for a nonobvious species related to a prior patented invention, even though the improvement falls within the claims of that prior patent. A prior genus which **does not explicitly** disclose a species does not anticipate a later claim to that species. This position is well supported by the holdings of the Federal Circuit. See, for example, *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 1262, 9 USPQ2d 1962, 1970 (Fed. Cir. 1989).

Applicants contend that the relationship between the pending claims and the cited art is largely analogous to the factual situation in the above example. Applicants assert that the presently claimed invention provides a particular combination of elements and constitutes a species. Applicants' species is unobvious and patentable over the generic teachings of Ingham et

al. because Ingham et al. fail to either teach or suggest the particular combination of elements recited in the pending claims.

Applicants contend that Ingham et al. fail to teach or suggest all the limitations set forth in the claims. Although Ingham et al. is broadly enabling and provides compositions and methods using *hedgehog* polypeptides, Ingham et al. fail to teach the benefits of the particular combinations of post-translational modifications, formulations, and mode of administration set forth in the pending claims. That is, although Ingham et al. broadly teach methods and compositions using *hedgehog* polypeptides, Ingham et al. provide no motivation to specifically select the particular post-translational modifications, the particular formulation, or the particular mode of administration, as presently claimed. MPEP 2144.08 outlines the guidelines for determining that a reference renders an invention obvious and directs the Examiner to “determine whether one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole, i.e., to select the claimed species or subgenus from the disclosed prior art genus.” Applicants contend that Ingham et al. fail to provide motivation to select the specific classes of post-translational modifications, the particular formulations, or the particular mode of administration. Furthermore, the Examiner has not provided any evidence or additional references that would have motivated one of skill in the art to arrive at Applicants’ invention.

Applicants maintain that Ingham et al. fail to satisfy the criteria necessary for anticipating or rendering obvious Applicants’ invention. The MPEP and a substantial body of case law clearly recognize the patentability of a species despite the presence of prior art to the genus, as is the case here. Accordingly, the claimed invention is patentable in light of the prior art, and reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

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Respectfully Submitted,



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